



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,817	09/17/2003	Harry A. Dugger III	3633-038-999	4051

24998 7590 07/08/2005

DICKSTEIN SHAPIRO MORIN & OSHINSKY LLP
2101 L Street, NW
Washington, DC 20037

EXAMINER

HAGHIGHATIAN, MINA

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,817

Applicant(s)

DUGGER, HARRY A.

Examiner

Mina Haghighatian

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/04/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the RCE, IDS and Remarks filed on 04/04/05 and the Amendments and Remarks filed on 04/29/05. Accordingly claims 14-22 are pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/04/05 has been entered.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14-17, 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deihl (WO 9413280) in view of Fassberg et al (EP 0656206A1).

Deihl teaches a sprayable analgesic composition comprising an analgesic compound which is absorbed into the bloodstream through the buccal mucosa and a pharmacologically acceptable liquid carrier. In a preferred embodiment the active agent

Art Unit: 1616

is ibuprofen and the liquid carrier is aqueous ethanol (see page 3). The formulation may also contain other ingredients such as surfactants, humectants, flavoring agents, etc (see page 4). The table in example I shows the concentration ranges of each ingredient. Deihl lacks disclosure of specific active agents for the said formulation.

Fassberg discloses aerosol, formulations for oral or nasal administration, which comprise a medicament, an excipient, propellant and optionally surfactants. The suitable excipients include alcohols, polyethylene glycols, short chain fatty acids, etc (see page 3). Fassberg discloses that any pharmaceutically active agent which can be delivered by oral or nasal inhalation may be used. Examples include antihistamines, antibiotics, steroids, bronchodilators, etc (see page 5, lines 42-50).

Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deihl (WO 9413280) in view of Fassberg et al (EP 0656206A1) and further in view of Kanios et al (5,719,197).

The combined references, discussed above, lack specific disclosure on aqueous polyethylene glycol and aqueous ethanol.

Kanios et al, discussed in detail in previous Office Actions, teaches formulations that can be in a spray format. The said formulations may contain any one or more of the active agents listed in columns 12-31, including antibiotics, antifungals, antiasthmatics,

Art Unit: 1616

etc. Examples of such active agents include cyclosporine, clozapine, erythromycin, ondansetron, cimetidine, etc.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made given the general teachings of Diehl's formulations for buccal mucosal administration, to have looked in the art for other specific solvents suitable for spray formulations of liquid carriers, as taught by Fassberg et al, with reasonable expectations of successfully preparing suitable formulations for various therapies. Furthermore it is obvious to one of ordinary skill in the art to have substituted any suitable active agent for the analgesics of Diehl's buccal spray formulations as claimed as taught by Kanios et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/537,118 in view of Kanios et al (5,719,197).

Claims of instant application recite a propellant free spray composition and a method of administering the said composition containing an active compound in the amount of 0.001 and 60% by weight and a polar solvent in an amount between 30 and 99% by weight of the total composition. The active agent is selected from a group of classes of active agents. Claims of the copending Application No. 09/537,118 recite the same propellant free spray composition and method of administration the said composition containing solvents and various active agents. It would have been obvious to modify the formulations to include various active agents as taught by Kanios et al to broaden the scope of therapy using the said spray formulation.

This is a provisional obviousness-type double patenting rejection.

The rejection of claim 20 under judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of US Patent No. 6,676,931 is maintained.

Response to Arguments

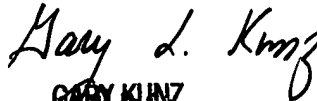
Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600



Mina Haghighatian
June 24, 2005